

EXHIBIT 1

PPE Specific ID: 0012841 | Rev:4
Labeling Supplement 28 Nov 2014
RMO #15506 Gynecare TVT54254
Device Release Level: 4. Production
GYNECARE TVT™

Tension-free Support
for Incontinence

GYNECARE TVT™
Tension-free Vaginal Tape

GYNECARE TVT™ Single Use Device
GYNECARE TVT™ Reusable Introducer
GYNECARE TVT™ Reusable Rigid Catheter Guide
GYNECARE TVT™ anordning til engangsbrug
GYNECARE TVT™ indfører til flergangsbrug
GYNECARE TVT™ stift guiding kateter til flergangsbrug
GYNECARE TVT™ hulpmiddel voor eenmalig gebruik
GYNECARE TVT™ herbruikbare introducer
GYNECARE TVT™ herbruikbare starre kathetervoerder
GYNECARE TVT™ -laite, kertokäyttöinen
GYNECARE TVT™ -sisäinjieja, kestopöytöinen
GYNECARE TVT™ -katetri johdair, kestopöytöinen, jäykkä
Dispositif GYNECARE TVT™ à usage unique
Introducteur réutilisable GYNECARE TVT™
Guide de sonde rigide réutilisable GYNECARE TVT™
GYNECARE TVT™ Einmal-Implantat
GYNECARE TVT™ wiederverwendbares Einführungsinstrument
GYNECARE TVT™ wiederverwendbare starre Katheterführung
Συσκευή μιας χρήσης GYNECARE TVT™
Επαναχρησιμοποιήσιμος εισαγωγέας GYNECARE TVT™
Επαναχρησιμοποιήσιμος άκαμπτος οδηγός καθετήρα
GYNECARE TVT™
Dispositivo monouso GYNECARE TVT™
Introduttore riutilizzabile GYNECARE TVT™
Guida rigida riutilizzabile per catetere GYNECARE TVT™
Dispositivo de utilização única GYNECARE TVT™
Introdução reutilizável GYNECARE TVT™
Guia rígido do cateter reutilizável GYNECARE TVT™
Sistema para un solo uso GYNECARE TVT™
Introducción reutilizable GYNECARE TVT™
Guía de catéter rígida reutilizable GYNECARE TVT™
GYNECARE TVT™ produkt för engångsbruk
GYNECARE TVT™ återanvändbar införare
GYNECARE TVT™ återanvändbar stel kateterguide



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PPE Specific AB-0012841 | Rev:4

13. During passage of the Needle, the Needle should be placed in the Needle tip towards the pre-marked abdominal exit site.

14. When the Needle Tip is positioned under the mid-urethra, the Needle should be pulled back slightly to ensure the GYNECARE TVT is introduced from the Needle. Before the Implant is pulled out, the Needle should be removed. The Needle should be removed and the Foley catheter should be inserted into the bladder. The Foley catheter should be secured to the leg and the patient should be monitored for any complications.

15. Once bladder integrity is confirmed, pull the Needle upward to bring the Implant out through the abdominal exit site. Clamp the Implant just below the Needle. Cut the Implant between the connection to the Needle and the clamp.

16. The procedure is now repeated on the patient's other side while repeating steps 9 – 15. NOTE: IN ORDER TO MINIMIZE THE RISK OF BLADDER INJURY, IT IS IMPORTANT THAT THE BLADDER BE DISPLACED TO THE CONTRALATERAL SIDE USING THE MANEUVERS OUTLINED IN STEP 10.

17. The ends of the implant are then pulled upward to bring the implant (sling) loosely, i.e., without tension, under the midurethra. Adjust the implant so that leakage is reduced, allowing only a few drops of urinary leakage to occur under stress. For this, use patient feedback, i.e. coughing with a full bladder (approximately 300 mL).

18. Grasp the Implant Sheaths that surround the Implant with clamps, taking care not to grasp the Implant. Then individually remove the Implant Sheaths by gently pulling up on the clamps, away from the abdomen, one at a time. To avoid putting tension on the Implant, a blunt instrument (scissors or forceps) should be placed between the urethra and the Implant during removal of the Implant Sheaths.

19. **NOTE: Premature removal of the sheath may make subsequent adjustments difficult.**

20. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture the implant.

21. Close the skin incisions with suture or surgical skin adhesive.

22. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE Mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT System before employing the GYNECARE TVT Device. It is important that the tape be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the GYNECARE TVT procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks.
- Retropubic bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from the hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The Rigid Catheter Guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- When removing the Rigid Catheter Guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.